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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,585	03/17/2004	Le Huang		3879

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EXAMINER	
RAO, DEEPAK R	
ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental Notice of Allowability	Application No. 10/802,585	Applicant(s) HUANG, LE	
	Examiner Deepak Rao	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed on December 19, 2006*.

2. ☒ The allowed claim(s) is/are *1,8,13-18,23-28 and 32*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Deepak Rao
Primary Examiner
Art Unit: 1624

SUPPLEMENTAL EXAMINER'S AMENDMENT

This amendment is in addition to the examiner's amendment of March 22, 2007. Applicant's attorney brought into attention an inadvertent typographical error in claim 28 and authorized the correction of the same by examiner's amendment.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Hui Min He-Huang on March 29, 2007.

The application has been amended as follows:

In claim 1, following 'diffraction pattern', insert -- is --.

In claim 23, line 1, following 'claim 18,', insert -- wherein the --.

In claim 24, line 1, following 'claim 18,', insert -- wherein the --.

In claim 24, line 1, delete "preferably".

In claim 28, line 2, delete "anhydrous amorphous".

(Copy of claims as amended are enclosed in the Appendix)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deepak Rao
Primary Examiner
Art Unit 1624

March 29, 2007

APPENDIX

Copy of claims as amended upon entry of the examiner's amendment(s):

1. (Currently amended) Anhydrous amorphous fluvastatin sodium, wherein its X-ray powder diffraction pattern is substantially in accordance with Figure 3.

2-7 (Cancelled)

8. (Previously amended) A process for preparation of anhydrous amorphous fluvastatin sodium of claim 1, comprising steps of:

(a) Dissolving crude or pure hydrate amorphous or crystalline form or their mixtures of fluvastatin sodium in a non-hydroxylic solvent;

(b) Adding a non-polar hydrocarbon anti-solvent or adding the dissolved fluvastatin sodium to the non-polar anti-solvent to precipitate out product;

and (c) removing the solvent by filtration to afford anhydrous amorphous fluvastatin sodium.

9-12 (Cancelled)

13 (Original). The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is chosen from a group of non-polar hydrocarbon solvents comprising n-hexane, cyclohexane or n-heptane.

14 (Original). The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is n-hexane.

15 (Original). The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is cylcohexane.

16 (Original). The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is n-heptane.

17. (Previously amended). The process according to any of claims 8 and 13-16, which comprises cooling the solution and isolating the precipitated anhydrous amorphous form by filtration or centrifuging.

18. (Previously amended). A process for the preparation of anhydrous amorphous fluvastatin sodium of claim 1 by dissolving crude or pure hydrate amorphous or crystalline forms or their mixtures of fluvastatin sodium in acetonitrile or in straight or branched alkanol containing 1-4 carbon atoms or a mixture of such alkanols under heating and isolating the anhydrous amorphous fluvastatin sodium precipitated after cooling.

19-22 (Cancelled)

23 (Currently amended). The process according to claim 18, wherein the alkanol solvent is selected from methanol, ethanol, isopropanol, butanol or their mixtures.

24 (Currently amended). The process according to claim 18, wherein the alkanol solvent is ~~preferably~~ selected from ethanol and isopropanol.

25 (Original). The process according to claim 18, which comprises using acetonitrile or a mixture of acetonitrile and one or more alkanols.

26 (Previously amended). The process according to claim 18, which comprises dissolving fluvastatin sodium in alkanols or acetonitrile at the boiling point of the solvent.

27 (Previously amended). The process according to any of claims 18 and 23-26, which comprises cooling the solution and isolating the precipitated anhydrous amorphous fluvastatin sodium by filtration or centrifuging.

28 (Currently amended). A pharmaceutical composition comprising an anhydrous amorphous ~~anhydrous amorphous~~ fluvastatin sodium of claim 1 and pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, solvent binder or stabilizer.

29-31 (Cancelled)

32 (Original) A pharmaceutical composition according to claim 28, in the form of a tablet, troche, powder, syrup, patch, liposome, injection, dispersion, suspension, solutions, capsule, cream, ointment or aerosol.

33 (Cancelled)